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REPORT ON RUTIN IN TABLETS

BY

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Forty-three samples of rutin tablets were received by the Associate Referee in response to his request to tablet manufacturers. Since requests were sent to every listed manufacturer, it is felt that the samples received represent, almost entirely, the available supply. These tablets varied from the relatively simple, uncompounded rutin tablet to tablets containing, in addition to rutin, as many as four other active ingredients. The other active ingredients encountered were ascorbic acid, aminophylline, barbiturates, mannitol hexanitrate, nitroglycerin, sodium nitrite, theobromine, and tincture cratageus. Most of the tablets were uncoated, but a few were

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covered with a colored sugar coating; two samples were dyed throughout. The weight of rutin per tablet varied from 10 mg. to 100 mg. The following method, a slight modification of the method of Porter, *et al.*[1], has been applied in the analysis of all the available samples.

METHOD

Determine the average weight per tablet by weighing not less than 20 tablets. Thoroughly powder the weighed tablets and weigh the equivalent of 40 mg of rutin into a 50 ml centrifuge tube. Add 0.1 ml of glacial acetic acid and approximately 15–20 ml of 95% ethanol. Suspend the powder in the solvent by stirring, and place in a water bath (70°C.) for 10 min. Stir occasionally during this extraction period. After heating, remove the stirring rod (wash with 95% ethanol) and centrifuge at approximately 2000 rpm for 10 min. After centrifugation, carefully decant the supernatant into a 100 ml vol flask (use a funnel). While the tube is still inverted in the funnel, wash off the lip with 95% ethanol. Repeat this extraction, starting at "Add 0.1 ml of glacial acetic acid," twice more. When the contents of the volumetric flask are at room temperature, dilute to 100 ml with 95% ethanol. Remove any precipitate that may form on cooling or standing by filtration. Transfer 10 ml of this extract to a 250 ml vol flask and dilute to vol with distilled water. Remove by filtration any precipitate that forms. Determine the absorbance of this aqueous dilution at 338.5, 352.5, and 366.5 millimicrons by means of a spectrophotometer. Use 1 cm absorption cells and employ a distilled water blank.

CALCULATIONS

Using the data obtained, the following calulations are made:

$$a_{352.5} = \frac{A_{352.5}}{bc}$$

where a = absorptivity; A = absorbance = Log (I_0/I); b = cell length in cm; and c = concentration of original sample in the final dilution in grams per liter.

$$R_1 = \frac{A_{338.5}}{A_{352.5}} = \text{ratio of absorbance at 338.5 and 352.5 m}\mu.$$

$$R_2 = \frac{A_{366.5}}{A_{352.5}} = \text{ratio of absorbance at 366.5 and 352.5 m}\mu.$$

If R_1 equals $0.909 \pm .009$ and R_2 equals $0.846 \pm .009$, the extracted material can be considered pure rutin and the weight (in mg) per tablet can be calculated by means of the following equation:

$$\text{mg Rutin} \cdot 3H_2O/\text{tablet} = \frac{a_{352.5}}{26.3} \times \text{av. wt./tablet (mg)}$$

Since pharmaceutical rutin[2] may contain up to 5% quercetin an "accept-

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[1] Porter, W. L., Brice, B. A., Copley, M. J., and Couch, J. F., U. S. Department of Agriculture, AIC-159, July 1947. (Processed) Eastern Regional Research Laboratory.

[2] National Formulary, 9th Edition, 1950, p. 440. American Pharmaceutical Association, Washington 7, D. C.

able" range is suggested for the above ratios: for R_1 a range of 0.890 to 0.918; for R_2 a range of 0.837 to 0.878. If the sample falls within these ranges the above equation may be used for calculating the rutin content. An increase in R_2 above this limit with a simultaneous decrease below the R_1 limit indicates that the sample contains more than 5% quercetin. In such cases the amount of rutin may be calculated from the following equation:

$$\text{mg Rutin3} \cdot \text{H}_2\text{O/tablet} = (0.1475a_{352.5} - 0.1292a_{366.5}) \times \text{av. wt./tablet (mg)}$$

An increase or decrease beyond the limits of both ratios indicates an interfering absorption which invalidates the analysis.

An increase of R_1 beyond its limit while R_2 remains within its range indicates an interfering absorption at 338.5 millimicrons which diminishes so as to be ineffective at the R_2 wavelength. Under these conditions the correctness of the observed value at 352.5 millimicrons is accepted because any elevation of the 352.5 millimicron reading would lower R_2.

DISCUSSION

Of the 43 samples analyzed, difficulty was encountered with only one sample. This contained a possibly incompatible ingredient and the interence is being studied further. Of the other 42 samples analyzed, 38 gave ratios within the above limits and the rutin content was within the pharmaceutical limit of $\pm 7.5\%$. Of the four that did not meet this requirement, three samples had acceptable ratios and their quantities were just outside the pharmaceutical limits. The fourth sample showed signs of decomposition prior to the analysis and is being studied further.

Under the conditions described in the method the sample weights involved were between 0.150 g and 2.0 g. The absorbance observed was between 0.350 and 0.460.

The Associate Referee intends to submit the method to collaborators.*

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* For report of Subcommittee B and action of the Association, see *This Journal*, 35, 47 (1952).